MEDORAH MEDITEK

MEDORAH®

INFLATION DEVICE

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

MEDORAH® Inflation Device

Intended Use / Indications for use

Intended use- MEDORAH® Inflation Device is to be used to facilitate the use of catheters and guidewires during interventional procedures. The MEDORAH® Inflation Device is designed to be used to inflate/deflate balloon catheters as well as to monitor pressure within the balloon.

Device Description

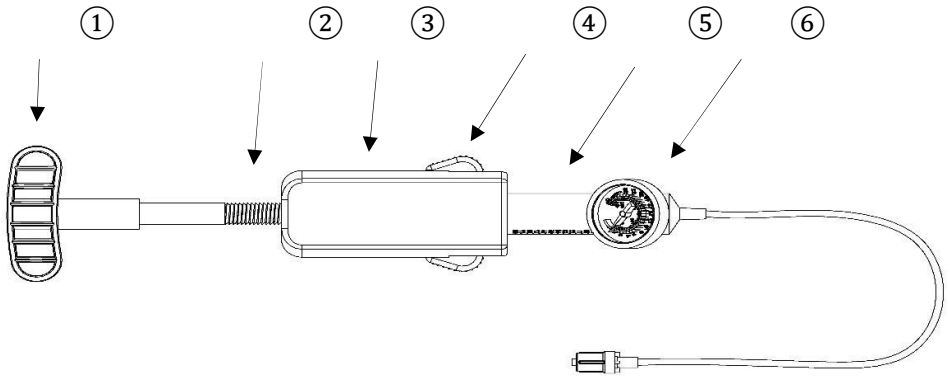
The MEDORAH® Inflation Device is a one-piece, plastic, disposable inflation device with a lock lever design that controls the piston, a manometer, and a connecting tube with a male rotating adapter. An optional 3-way stopcock may also be enclosed for use during preparation of the device. The manometer measures pressures ranging from vacuum to gauge capacity; the gauge is marked in 1 atm increments. The gauge also has an inner scale of comparable PSI measurements. The accuracy of the manometer has been determined to be within 1 atm over the range.

MEDORAH® Inflation Device Specifications

Rated Volume

(ml): 20 Max

Pressure (atm): 30



①	Handle
②	Spring
③	Outer Case
④	Releaser
⑤	Syringe
⑥	Pressure Gauge

Contraindications
Not known

Warnings

- For single use only. Do not **reuse, reprocess or re-sterilize**. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Precautions

- Always follow the manufacturer's directions accompanying the balloon catheter for instructions for use, maximum inflation pressure, precautions, and warnings for use.
- The pressure displayed on the inflation device must not exceed maximum recommended balloon catheter inflation pressure.

Procedure

Preparation:

All aspiration and injection movements should be performed with the lock lever pressed to the left, or unlocked.
Press the lock lever to the left to release the piston. You can freely move the piston back in this position for aspiration or push it forward in this position for injection.
Slide the lever to the straight up position in order to lock the piston into place.

1. In a small sterile bowl, mix contrast medium and regular saline to a solution. For recommendations on a particular contrast combination, see the instructions for the balloon catheter and the contrast medium.
2. Lower the tubing into the contrast medium by an angle.
3. To fill the syringe, aspirate enough solution by pushing the release lever to the left. Attach the stopcock if necessary.
4. To remove air from the syringe and connected line, hold the device upright. If required, gently tap the syringe to eliminate any air bubbles and fully fill the connecting line.
5. Check to make sure any air bubbles have been removed from the syringe, tubing, and stopcock, if applicable.
6. To get the right amount, adjust the syringe's volume. If further contrast is required, aspirate after immersing the syringe tip in the solution basin. (Close the stopcock, if necessary.)

Attaching the inflation device to the balloon dilation catheter:

1. As directed by the manufacturer, prepare and test the balloon dilation catheter.
2. Take out the syringe if it was used to prepare the balloon catheter.
3. A stopcock should be opened and purged with contrast material from the inflating device after it is put on the end of the connecting tube to remove any air.
4. A drop of contrast solution from the syringe should be inserted into each hub to form a fluid-fluid connection between the balloon and the stopcock or connecting tube (male rotating adapter) of the inflation device.
5. Securely tighten the hubs by hand.

Operating inflation device:

1. Let the piston advance into neutral position (0 atm) by releasing the lock lever.
2. In order to inflate the balloon, crank the piston's handle steadily clockwise until the necessary inflation pressure is obtained. Then, engage the lock lever. The lock lever keeps the pressure from rising.
3. Turn the piston's handle steadily counterclockwise until the required deflation pressure is attained to gradually deflate the balloon.

4. Pull back after pushing the lock lever to the left, releasing the piston, to quickly deflate the balloon. If desired, slide the lock lever back to lock.

Change of performance

If the device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

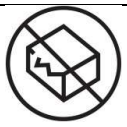
Disposal of a used device

After use, this product may be a potential biohazard. It must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of user.

Storage

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment. Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

Explanation of Symbols

	Date of Manufacture		Use-By Date
	Catalogue Number		Do not re-use
	Consult instructions for use		Caution
	Keep away from sunlight		Batch Code
	Do not use if package is damaged		Manufacturer
	Non-Pyrogenic		Keep dry

	Do Not resterilize		Sterilized using Ethylene Oxide

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and Medorah Meditek Pvt. Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.

MEDORAH MEDITEK

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